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Gopinathan K. Menon

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AVON PRODUCTS, INC.  
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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

06/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT.DEPARTMENT@AVON.COM

<b>Office Action Summary</b>	<b>Application No.</b> 09/521,442	<b>Applicant(s)</b> MENON, GOPINATHAN K.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 21 April 2009.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 36,38-40,42-44,46-48 and 50-54 is/are pending in the application.

    4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 36,38-40,42-44,46-48 and 50-54 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.

4) ☐ Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Summary*

Receipt of Applicant's Remarks and Claim Amendments filed on 04/21/09 is acknowledged. Claims 36, 38-40, 42-44, 46-48 and 50-54 are pending. Claims 36, 38-40, 42-44, 46-48 and 50-54 are rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/09 has been entered.

### **First Action Final**

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **MAINTAINED REJECTIONS**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. How to make the composition is not taught in the instant specification and as no correlation exists between *in vivo* and *in vitro*; the instant specification only provides written description for perilla oil used in treating cells. The results are not commensurate with the scope of the

instant claims, as the specification teaches that 'aged' or 'stored' perilla oil gives rise to the unexpected results with respect to PPAR activity (pg. 6, lines 7-13) and 'stored' perilla oil is not instant claimed. The art US 5,312,834 teaches a composition of perilla oil for treating the skin with this function that should have the same activity, but the instant specification teaches that it does not. As such the claims lack written description.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 36, 38-40, 42-44, 46-48, and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 36, 38-40, 42-44, 46-48, and 50-51 fail to correspond in scope with that which applicant regard as the invention can be found in the specification filed 3/7/2000. In that paper, applicant has stated (pg. 6, lines 7-13) that "It is surprising and unexpected that perilla oil inhibits up regulation by PPAR agonists, as perilla oil itself contains PPAR agonists such as linolenic acid and linoleic acid. This may be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids. The oxidation process may alter the PPAR stimulating activity of linolenic acid and linoleic acid...", and this statement indicates that the invention is different from what is defined in the claim(s) because the instant claims do not require that perilla oil is 'aged' or stored for a certain amount of time prior to

application on the cellulite. The instant claims suggest instead that fresh perilla oil treats cellulite. This is not what the instant specification teaches and as such there is a failure to claim the invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 38-40, 42-44, 46-48, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,945,109 ('109) in view of US 5,312,834 ('834).

The instant claims are drawn to a method of ameliorating or treating cellulite, comprising topically applying a composition comprising from about 0.01 wt% to about 10 wt% perilla oil to an area of skin affected by cellulite.

- '109 teaches a cosmetic product for topical administration for cellulite (abstract). '109 teaches that the cosmetic product comprises a topical application of an ointment, gel, cream, etc and that formulations include essential oils and plant extracts (col. 5, lines 31-54).
- '109 teaches that the product is topically applied once to twice daily (col. 6, lines 6-25).

- '109 example 1 teaches a groundnut oil added at 10% by weight to a cellulite cream.
- '109 does not teach perilla oil, but does teach essentials oils and plant extracts.
- '834 teaches that various creams and ointments for the skin contain chemicals that cause severe allergic reactions and can complicate skin problems (col. 1, lines 13-24 and col. 3, lines 17-28) and that a composition comprising perilla oil which has no side effects effectively treats skin and provides for good color and resilience of skin (col. 3, lines 41-47 and col. 5, lines 63-67). Examples teach that the perilla oil is from perilla seed of *Perilla frutescens* var. Further, '834 teaches that the 'aesthetic' appearance of skin is improved over time (Examples).

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

"[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct.

1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine ‘109 in view of ‘834. One of ordinary skill in the art would have been motivated to combine the teachings of ‘109 and ‘834, since many people are known to have allergic reactions as taught by ‘834 and ‘834 teaches that perilla oil is safe and has no side effects. ‘109 teaches a topical cream for the treatment of cellulite that includes plant oils, while ‘834 teaches perilla oil is specifically beneficial to healing skin conditions and inflammation to yield resilient and good colored skin. One would have a reasonable expectation of success in substituting a safe plant oil such as perilla oil of ‘834 which has no known side effects for groundnut oil of ‘109 to obtain the composition of ‘109 in view of ‘834.

### ***Response to Arguments***

Applicant's arguments with respect to claims 36, 38-40, 42-44, 46-48 and 50-54 have been considered but are not persuasive. Applicant's argue that the Examiner erroneously concludes that the perilla oil be aged or stored and that instead their invention is directed to fresh unaged perilla oil. The Examiner respectfully points out that the instant specification only teaches that aging/oxidized perilla oil is the reason for its unexpected properties. Silence of the instant examples about the age of the perilla oil is not a teaching away from use of aged perilla oil. Further, Applicant has improperly used Amgen v Hoeschet Marion Roussel, Inc (response pg. 5, 2<sup>nd</sup> paragraph), as it teaches that if another or other ways are disclosed in the specification as possible



modes of operation even if its not the best mode that the claims do not have to be limited to the best mode but can claim any disclosed mode. However, the instant Application does not teach any other option/way for the unexpected results other than "stored"/"aged" perilla oil to produce the unexpected results and thus clearly teaches that "stored"/"aged" perilla oil is the only disclosed mode. The use of '834 as a reference is to show that Applicant claims that prior art does not recognize perilla oil to treat skin impurities (instant specification pg. 3, lines 1-10), when in fact '834 does teach perilla oil treat skin impurities and that the composition also contains fish oil is not a teaching away from the instant claims which have the open 'comprising' language (abstract, Examples).

The written description issue also remains as there is no correlation between *in vivo* and *in vitro* results and the instant specification only describes treating cells with the composition, not topical application onto the skin as is instant claimed. Applicant argues that the 112 rejection relating to no correlation between *in vivo* and *in vitro* results is improper and that US 6,852,343 was patented by the office and discloses topical oil for cellulite treatment which reduces PPAR for *in vitro* models and thus is correlated to *in vivo*. The Examiner respectfully points out that each and every case is considered on its own merits and the patent does not teach perilla oil for treatment of cellulite and therefore is not pertinent to this case. As such the 112 rejections are maintained.

Applicant's argue that there is no prima facie case of obviousness and no motivation to combine '109 and '834, and the examiner respectfully points out that applicant's argue against the references individually, one cannot show nonobviousness

by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that '834 is directed to oral formulations and not topical and therefore is irrelevant. It should be noted that the motivation to combine references can be different from the ones set forth by Applicant. That is, as long as motivation exists to combine the elements, the problem to be solved does not have to involve the same reason for making the anti-cellulite cream of '109 with the perilla oil of '834. '109 is relied upon to teach the composition for topical administration via cream, ointment, etc for treatment of cellulite using essential oils and plant extracts, while '834 is relied upon solely for the teaching that various creams and ointments for the skin contain chemicals that cause severe allergic reactions and can further complicate skin problems, but that perilla oil is safe and effective for treating skin impurities to improve 'aesthetic' appearance of skin (col. 1, lines 13-24, col. 3, lines 41-47 and col. 5, lines 63-67); as such as skilled artisan who is not an automaton would know how to substitute one plant oil (groundnut) for another (perilla of '834), especially since perilla oil is taught to be safe, and not cause allergic reactions. As such, the Examiner respectfully submits that there is motivation to combine the teachings of '109 in view of '834 and the expected result of topical cream for treating cellulite comprising perilla oil.

Applicant also argues that they have provided art Hourihane et al that teaches that crude peanut oil is the cause of allergies and not refined and that Examiner has not provided proof that groundnut oil causes allergies, however the '834 teaches that cream, ointments, etc for treating skin inflammation often cause skin allergies and

complicate the skin problem, but that perilla oil overcomes this. However as previously provided, please again review the cited as interest (below) for proof that a skilled artisan would know that peanut oil (crude and refined) both cause allergic reactions, even death.

Lastly, it appears that prosecution has reached an impasse and Applicant may wish to exercise their right to appeal to the Board of Patent and Appeals and Interferences to render an ultimate decision.

#### **CITED AS INTEREST**

Olaszewski et al (1998) teaches that peanut oil contains allergenic proteins in both crude and refined peanut oil (abstract and conclusion pg. 858) and that peanut oil has been responsible for deaths (intro. 2<sup>nd</sup> column pg. 850).

Moneret-Vautrin et al (1998) teaches that the role of residual allergenic proteins in peanut oil is established by positive skin prick tests to proteic extracts from peanut oil and by double-blind placebo controlled challenges to peanut oil and that the presence of peanut oil allergens can contribute to the occurrence or persistence of symptoms (Summary pg. 1113). The art also teaches that avoidance of peanut oil is recommended and that creams and ointments containing peanut oil are not recommended (discussion pg. 1118).

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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